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2600 Bull Street
Columbia, SC 29201-1708

April 23, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Regarding: Docket No. 98N-1170

Dear Sir/Madame:

Enclosed are comments regarding the intent to propose amendments to the performance standard for sunlamp products, 21 CFR Part 1020.

Recommended Exposure Schedule. Your concerns are shared that inadequate attention is being paid to the recommended exposure schedule. The FDA should confirm, through their own or independent testing, that the test data being submitted is accurate. It is also imperative that lamps are tested consistently by all manufacturers by a detailed and reproducible procedure. The FDA must take the initiative to develop these procedures with input from the tanning equipment manufacturers.

One item that has been observed to be missing from most exposure schedules, users' instruction manuals and from the 1986 "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products" is the stipulation that all exposures be spaced at least 24 hours apart. It is imperative that this statement be added to all labeling if no other spacing is mentioned.

Adequacy of warnings on sunlamp products. The concern is noted about the warning being too long and detailed. However, it is felt that other potential health effects need to be addressed, and further emphasis be added regarding skin cancer. It is recommended that the warning be expanded and made larger. Requiring it to be in a contrasting color from the rest of the label would be helpful. Our state currently requires a posted warning identical to the one in the performance standard, but we are in the process of updating our tanning facility regulations and we propose to have the additional warnings added to our posted warning requirement. The following wording should be considered:

98N-1170 C2

"DANGER - ULTRAVIOLET RADIATION

Follow instructions. Avoid too frequent or lengthy exposure. As with natural sunlight, exposure can cause serious skin injury and allergic reactions. Repeated exposure may cause chronic sun damage characterized by wrinkling, dryness, fragility and bruising of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR. FAILURE TO USE PROTECTIVE EYEWEAR IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Ultraviolet radiation from sunlamps will aggravate the effects of the sun. Do not sunbathe before or after exposure to ultraviolet radiation. Certain foods, medications (including, but not limited to, tranquilizers, diuretics, antibiotics, high blood pressure medication, birth control pills and skin creams), cosmetics or toiletries may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. Pregnant women or women who are using birth control pills who use this product may develop discolored skin. If you do not tan in the sun, you are unlikely to tan from the use of this product."

We are in agreement that chronic, less intense exposures to ultraviolet radiation contribute to skin cancer and other health effects. It has been observed that virtually nothing has been done by the tanning industry to stop the rampant allowance and advertisement of daily or unlimited tanning. It is strongly suggested that the FDA add a statement about the potential deleterious effects of this practice in bold to the warning statement in wording that is even stronger and more direct than "Avoid too frequent or lengthy exposures."

We do not feel the scientific evidence is strong enough to add a warning about melanoma, so it is recommended that a statement regarding melanoma is not added to the warning.

It is agreed that including a reproduction of the text of the warning statement in catalogs, etc., would be useful to warn potential purchasers of tanning equipment.

Replacement lamps. We have observed much confusion among the regulated community regarding choosing an equivalent replacement lamp. Some type of grading or rating system based upon biological efficacy would probably be helpful. This would also take into account the deeper penetration into the skin, thus additional potential adverse health effects, caused by high pressure lamps. However, I feel the root of the problem is the fact that there is apparently no oversight or enforcement by the FDA towards the lamp manufacturers or distributors. I am constantly being told that distributors do not want to conduct business in our state because we enforce the FDA's lamp equivalency regulations. In my opinion, all manufacturers and distributors must be made to comply with the FDA regulations. This responsibility rests solely upon the FDA. Our state would gladly assist the FDA by reporting problem vendors; however, our assistance has never been requested. Again, the FDA should confirm, through their own or independent testing, that the test data being submitted is accurate. Again, it is also imperative that

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Did You Know?

- Each South Carolinian generates 4.2 pounds of household garbage per day
- Households and industry recycled 27% of the garbage generated in FY '96. That's up from 16% in 1995! Keep up the good work - recycle this envelope.
- 30% of solid waste is food packaging. Buying products in recycled packaging or reduced packaging helps save valuable landfill space, energy and natural resources.